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Section 5

510(k) Summary

Aspire CR for Mammography (CRm) FFDM System

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FUJIFILM
Fujifilm Medical Systems, USA

DEC - 8 2011

510(k) Summary
Aspire CR for Mammography (CR*m*) FFDM System

Date: June 10, 2011

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut, 06902, U.S.A.

Contact Person:

Name:	Debra Peacock
Title:	Regulatory Affairs Manager
Telephone:	(203) 602-3774
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Identification of the Proposed Device:

Proprietary/Trade Name:	Aspire CR for Mammography (CR*m*) FFDM System
Classification Name:	Full Field Digital Mammography System
Regulations Number:	21 CFR 892.1715
Product Codes:	MUE
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Full Field Digital Mammography System

1. INDICATIONS FOR USE

The Aspire CR for Mammography (CR*m*) System is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Fuji Aspire CRm System is intended to be used in the same clinical applications as traditional film/screen systems.

2. DEVICE DESCRIPTION

The FCR Aspire CR*m* is Fuji's newest reader to join our CR for mammography (FCR*m*) line of mammography readers (ClearView CS*m* and ClearView 1-*m*). The Aspire CR*m* system is composed of an Aspire CRm image reader, a new 50 micron HR VI single sided image plate (IP), and the same Fuji Flash Plus IIP*m* acquisition workstation as our approved FCRMS. In addition, any cleared dedicated mammographic x-ray machine may be used with the Aspire CR*m* system to generate digital mammographic images for screening and diagnosis of breast cancer. The mammographic images can be interpreted by a qualified physician using either hardcopy film or softcopy display at a 5

megapixel 510(k) cleared for mammography soft copy review station, and optionally printed on a 510(k) cleared for mammography printer.

The requirements for the dedicated mammographic x-ray machine are as follows:

- An x-ray machine specifically designed and 510(k) cleared for mammography should be used.

- The X-ray tube should have as a minimum a molybdenum target and molybdenum filter
- (Mo/Mo) combination for calibration of the Aspire CR*m* image reader and optionally any of the following anode target and filter combinations: molybdenum target with rhodium filter (Mo/Rh), rhodium target with rhodium filter (Rh/Rh), and tungsten target with rhodium filter (W/Rh).

- The x-ray system should have both manual exposure control and automatic exposure control (AEC). The AEC may be of the type controlling mAs only, or mAs and kVp, or mAs, kVp and filter, or mAs. kVp. filter, and target.

3. PREDICATE DEVICES

	Proposed Fujifilm Aspire CRm	Predicate Kodak DirectView CR Mammography System (P080018)	Predicate Fuji CR for Mammography System (FCRMS) (P050014)
Detector-only FFDM System	Yes	Yes	Yes
Acquisition Workstation	Fujifilm Flash Plus IIPm (CR-IR348 CL) Mammography Workstation specifically designed for viewing and storing images and data. Fuji proprietary software.	Yes. CARESTREAM (KODAK) Mammography Workstation specifically designed for viewing and storing images and data. Carestream (Kodak) proprietary software.	Same. Fujifilm Flash Plus IIPm (CR-IR348 CL) Mammography Workstation specifically designed for viewing and storing images and data. Fuji proprietary software.
Image Reader	Aspire CRm (CR-IR359) single slot reader can be used for both mammography and general radiography.	Yes. Single slot reader(s) can be used for both mammography and general radiography.	ClearView CSm (CR-IR363) multi slot reader and ClearView-1m (CR-IR368) single slot reader can be used for both mammography and general radiography.
Detector	Flexible, Single Sided Imaging Plate (IP)	Rigid, Single Sided IP	Flexible, Dual Sided IP

4. SUMMARY OF STUDIES

Preclinical Studies:

The following Preclinical tests were performed in accordance with Section 8 of the Class II Special Controls Guidance Document: Full-Field Digital Mammography System Document issued on: November 5, 2010.

- Sensitometric Response
- Spatial resolution of Aspire CRm
- Aspire CRm Noise Analysis
- Aspire CRm Detective Quantum Efficiency
- Dynamic Range-NEQ
- Dynamic Range-DQE
- Image Erasure and Fading Test for Aspire CRm
- Image Fogging Test for Aspire CRm
- ACR Phantom (2cm, 4.2cm, and 6cm) Scoring
- CD MAM Scoring
- Aspire CRm (HR-VI) / Kodak DirectViewCR (EHR-M2) MTF Comparison
- Aspire CRm (HR-VI) / Kodak DirectViewCR (EHR-M2) DQE Comparison

The results of the tests demonstrate that our proposed device is substantially equivalent to our cleared predicate devices. The Aspire CRm system performed as well as the predicate devices in all relevant areas. As recommended by FFDM Guidance Document, and where appropriate, tests were performed in accordance with IEC 62220-1-2 and The Addendum on Digital Mammography: The European Protocol for the Quality Control of the physical and technical aspects of mammography screening, version 1.0, November 2003.

Clinical Images Studies:

An image attribute evaluation was conducted in accordance with the Class II Special Controls Guidance Document: Full-Field Digital Mammography System Guidance Document, dated November 5, 2010, which concluded that the images were of sufficiently acceptable quality for clinical mammographic usage.

5. SUBSTANTIAL EQUIVALENCE

The Aspire CRm FFDM System is substantially equivalent to the predicate device, Kodak DirectView CR Mammography System (P080018) and our own Fuji CR for Mammography System (FCRMS). The Aspire CRm uses the same acquisition workstation as our currently approved FCRMS. Our FCRMS uses a dual sided 50 micron high resolution image plate. The Aspire CRm uses a new, single sided 50 micron, high resolution image plate (HR VI). Kodak's also uses a single sided 50 micron image plate. All systems are a detector-only FFDM (Computed Radiography for Mammography) system, using any cleared dedicated x-ray mammography system.

6. CONCLUSION

The Aspire CRm FFDM System is substantially equivalent to the predicate devices in respects to indication for use, technology, similar materials and image quality. All three systems are CR for mammography systems utilizing an imaging plate and CR image reader. All systems demonstrate comparable safety and effectiveness features, and are similar in design and construction.

All collected performance data demonstrate that the devices are substantially equivalent. Our conclusion is that the Aspire CRm FFDM System is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Ms. Debra A. Peacock
Regulatory Affairs Manager
FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
STAMFORD CT 06902

Re: K111646
Trade/Device Name: Aspire CR for Mammography (CRm) System
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: November 11, 2011
Received: November 14, 2011

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: *Aspire CR for Mammography (CRm) System

Indications for Use:

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Prescription Use__X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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